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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/764,833

01/27/2004

Michal Ayalon-Soffer

27256

8418

7590

08/29/2006

Martin D. Moynihan
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EXAMINER

WHALEY, PABLO S

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 08/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/764,833	AYALON-SOFFER ET AL.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-209 is/are pending in the application.
- 4a) Of the above claim(s) 1-7,9-13 and 15-209 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>11/22/04; 10/19/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

APPLICANTS' ELECTION

Applicants' election with traverse of Group II drawn to Claims 14, 27, 28, 33, 46-47, 52, 65-66, 71, 84-85, 90, 103-104, 109, 122-123, 128, 141-142, 147, 160-161, 166, 177-178, 183, 196-197, and 202, and election of SEQ ID No: 1, filed 05/31/2006, is acknowledged. Applicants traverse that claim 8, also drawn to isolated polypeptides, should also be included in Group II is persuasive. Claim 8 is hereby included in Group II. The requirement is still deemed proper and is therefore made FINAL.

Newly submitted claims 208 and 209 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 208 and 209 are directed to polynucleotides coding for polypeptides, which are different chemical types than the polypeptides of claims 8 and 14. Accordingly, claims 208 and 209 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-7, 9-13, and 15-209 are hereby withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 05/31/2006.

CLAIMS UNDER EXAMINATION

Claims herein under examination are Claims 8 and 14 as they read on the elected species. An action on the merits follows.

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PRIORITY

Priority to US Provisional Application 60/322285, filed 09/14/2001, and 60/322359, filed 09/14/2001, has been denied because the priority documents do not disclose SEQ ID NO: 1.

DRAWINGS

Drawings filed 1/27/04 have been accepted.

ABSTRACT

The abstract of the disclosure is objected to because it contains hyperlinks. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01(b).

INFORMALITIES

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 2, 3, and elsewhere. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

INFORMATION DISCLOSURE STATEMENT

The information disclosure statements filed 10/19/2005 and 11/22/2004 have been considered in full.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8 and 14 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either an asserted utility or a well-established utility.

In the instant case, the specification sets forth a utility for novel soluble polypeptides and polynucleotides encoding the polypeptides in the diagnosis and treatment of a wide range of diseases [Specification, p. 23 and 26]. However, this utility is generic to the class of Met polypeptides. Therefore, the disclosed utility is not specific to the claimed sequence. Other well-established utilities have been disclosed in the Specification (e.g. Met splice variants that can serve as an inhibitor of Met-HGF interaction [p.81], however they are not specific to the claimed sequence.

Claims 8 and 14 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a well asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

WRITTEN DESCRIPTION

Claim 8 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 8 and 14 recites the limitation "an isolated polypeptide as set forth in SEQ ID NO: 1." While the specification discloses "novel polypeptides, which are encoded by the isolated polynucleotide and respective nucleic acid fragments," there is no disclosure indicating the applicant's have actually identified any fragments as recited in instant claim 8. Therefore, the description lacks sufficient detail as to the actual fragments specific to SEQ ID NO: 1, such that one of skill in the art would have been aware that applicants were actually in possession of such "products" at the time of invention.

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "as set forth in SEQ ID NO: 1". The Specification does not define the term "as set forth", therefore Claim 8 is vague and indefinite as to the metes and bounds of "as set forth in SEQ ID NO: 1." The Examiner is interpreting "as set forth in" to be open claim language, equivalent to "comprising". Clarification is requested.

Claim 14 recites "as determined using the LALIGN software of EMBnet Switzerland." Because of the use of a proper name, it is unclear whether the name used to identify the sequence is a tradename or trademarked term. It is noted that use of tradenames render claims

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indefinite as such names can change over time or may be used to refer to a plurality of different methods, and it is unclear what steps are intended to be encompassed by the tradenamed method. Clarification is requested.

Claim 14 recites an embedded hyperlink (line 3), therefore it is unclear in what way this limitation further limits the sequence of claim 14. It is noted that use of hyperlinks render claims indefinite as such links may change over time. Clarification is requested.

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 8 and 14 are rejected under 35 U.S.C. 102 (e) as being anticipated by Muller et al. (US PUB 20030118585A1; Filed: 10/17/2001).

Muller et al. teach an isolated polypeptide sequence wherein SEQ ID No. 12 is 97.6% identical to instant SEQ ID No. 1, thereby anticipating claims 8 and 14. It is noted that the

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Specification does not define "as set forth in SEQ ID NO: 1", therefore any fragment of the sequence taught by Muller et al. may be used to anticipate SEQ ID NO: 1 of instant claim 8.

Claims 8 and 14 are rejected under 35 U.S.C. 102 (b) as being anticipated by Park et al. (Proc. Natl. Acad. Sci. U.S.A., 1987, Vol. 84, p. 6379-6383, Accession # A28303).

Park et al. teach an isolated polypeptide sequence wherein residues 1-755 are 97.6% identical to instant SEQ ID No. 1, thereby anticipating claims 8 and 14. It is noted that the Specification does not define "as set forth in SEQ ID NO: 1", therefore any fragment of the sequence taught by Giordano et al. may be used to anticipate SEQ ID NO: 1 of instant claim 8.

CONCLUSION

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner
Art Unit 1631
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See A. Con
Patent Examiner
8/21/04